Vyvgart® Hytrulo (efgartigimod alfa-fcab and hyaluronidase-qvfc)
(Subcutaneous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 12 months thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- CIDP: 504 billable units weekly
- gMG: 504 billable units weekly for 4 doses per 56 days

III. Initial Approval Criteria

Target Agent(s) will be approved when ALL of the following are met:

- ONE of the following:
  - The patient has a diagnosis of generalized Myasthenia Gravis (gMG) AND ALL of the following:
    - The patient has a positive serological test for anti-AChR antibodies (medical records required); **AND**
    - The patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II-IVb; **AND**
    - The patient has a MG-Activities of Daily Living total score of greater than or equal to 5; **AND**
    - ONE of the following:
      - The patient's current medications have been assessed and any medications known to exacerbate myasthenia gravis (e.g., beta blockers, procainamide, quinidine, magnesium, anti-programmed death receptor-1 monoclonal antibodies, hydroxychloroquine, aminoglycosides) have been discontinued; **OR**
      - Discontinuation of the offending agent is NOT clinically appropriate; **AND**
    - ONE of the following:
      - The patient has tried and had an inadequate response to at least ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine,

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cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide); **OR**

- The patient has an intolerance or hypersensitivity to ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide); **OR**
- The patient has an FDA labeled contraindication to ALL conventional agents used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide); **OR**
- The patient required chronic intravenous immunoglobulin (IVIG); **OR**
- The patient required chronic plasmapheresis/plasma exchange; **AND**

- The patient will NOT be using the requested agent in combination with Rystiggo (rozanolixizumab-noli), Soliris (eculizumab), Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Zilbrysq (zilucoplan), Vyvgart (efgartigimod alfa-fcab), or Imaavy (nipocalimab-aahu); **OR**

- The patient has a diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP), AND ALL of the following:
  - The patient's disease course is progressive or relapsing and remitting for at least 2 months; **AND**
  - The patient has progressive or relapsing motor sensory impairment of more than one limb; **AND**
  - The patient has electrodiagnostic findings indicating demyelination with at least ONE of the following:
    - Prolonged distal motor latency in at least 2 motor nerves; **OR**
    - Reduced motor conduction velocity in at least 2 motor nerves; **OR**
    - Prolonged F-wave latency in at least 2 motor nerves; **OR**
    - Absent F-wave in at least 2 motor nerves plus one other demyelination criterion listed here in at least 1 other nerve; **OR**
    - Partial motor conduction block in at least 2 motor nerves or in 1 nerve plus one other demyelination criterion listed here; **OR**
    - Abnormal temporal dispersion conduction in at least 2 motor nerves; **OR**
    - Distal CMAP duration increase in at least 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve; **AND**
  - The patient has ONE of the following:
    - Tried and had an inadequate response to at least a 3-month trial of ONE standard of care therapy (i.e., corticosteroids, immunoglobulins, plasma exchange); **OR**

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        - An intolerance or hypersensitivity to ONE standard of care therapy (i.e., corticosteroids, immunoglobulins, plasma exchange); **OR**
        - An FDA labeled contraindication to ALL standard of care therapies (i.e., corticosteroids, immunoglobulins, plasma exchange); **OR**
    - The patient has another FDA labeled indication for the requested agent and route of administration; **AND**
- If the patient has an FDA labeled indication, then ONE of the following:
    - The patient's age is within FDA labeling for the requested indication for the requested agent; **OR**
    - There is support for using the requested agent for the patient's age for the requested indication; **AND**
- The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis; **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**
- The requested quantity (dose) is within FDA labeled dosing for the requested indication

IV. Renewal Criteria

Target Agent(s) will be approved when ALL of the following are met:

- The patient has been previously approved for the requested agent through the plan's Medical Drug Review process (Note: patients not previously approved for the requested agent will require initial evaluation review); **AND**
- The patient has had clinical benefit with the requested agent; **AND**
- The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis; **AND**
- The patient will NOT be using the requested agent in combination with Rystiggo (rozanolixizumab-noli), Soliris (eculizumab), Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Zilbrysq (zilucoplan), Vyvgart (efgartigimod alfa-fcab), or Imaavy (nipocalimab-aahu); **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**
- The requested quantity (dose) is within FDA labeled dosing for the requested indication

V. Dosage/Administration

Indication	Dose
Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)	**Single-Dose Prefilled Syringe** Administer 1,000 mg / 10,000 units (1,000 mg efgartigimod alfa and 10,000 units hyaluronidase) subcutaneously over approximately 20 to 30 seconds as

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	once weekly injections. **Single-Dose Vial** Administer 1,008 mg / 11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) subcutaneously over approximately 30 to 90 seconds as once weekly injections.
Generalized Myasthenia Gravis (gMG)	**Single-Dose Prefilled Syringe** Administer 1,000 mg / 10,000 units (1,000 mg efgartigimod alfa and 10,000 units hyaluronidase) subcutaneously over approximately 20 to 30 seconds in cycles of once weekly injections for 4 weeks. **Single-Dose Vial** Administer 1,008 mg / 11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) subcutaneously over approximately 30 to 90 seconds in cycles of once weekly injections for 4 weeks. ****NOTE:*** Administer subsequent treatment cycles based on clinical evaluation, but no sooner than 28 days from the last administration of the previous treatment cycle.
Note: • ***Single-Dose Prefilled Syringe:*** *May be administered by patients and/or caregivers after proper instruction in subcutaneous injection technique* • ***Single-Dose Vial:*** *Must be administered by a healthcare professional only.*	

VI. Billing Code/Availability Information

HCPCS Code:

- J9334 – Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc; 1 billable unit = 2 mg

NDC(s):

- Vyvgart Hytrulo 1,008 mg efgartigimod alfa and 11,200 units hyaluronidase per 5.6 mL (180 mg/2,000 units per mL) single-dose vial: 73475-3102-xx
- Vyvgart Hytrulo 1,000 mg efgartigimod alfa and 10,000 units hyaluronidase per 5 mL (200 mg/2,000 units per mL) single-dose prefilled syringe: 73475-1221-xx

VII. References

1. Vyvgart Hytrulo prescribing information. Argenx US, Inc. October 2025.
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5. Van Den Bergh PYK, Van Doorn PA, Hadden RDM, et al. European Academy of Neurology/Peripheral Nerve Society guideline on diagnosis and treatment of chronic inflammatory demyelinating polyradiculoneuropathy: Report of a joint Task Force—Second revision. Journal of the Peripheral Nervous System. 2021;26(3):242-268. doi:10.1111/jns.12455.
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8. Jayam Trouth A, Dabi A, Solieman N, Kurukumbi M, Kalyanam J. Myasthenia gravis: a review. Autoimmune Dis. 2012;2012:874680. doi:10.1155/2012/874680.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation
G61.81	Chronic inflammatory demyelinating polyneuritis
G61.89	Other inflammatory polyneuropathies
G62.89	Other specified polyneuropathies

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Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdictio	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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